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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/822,496 | 04/12/2004 | Larry F. Lemanski | 6818-70 | 3665 |

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| EXAMINER | |
|---|---|
| TSAY, MARSHA M | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1653 | |

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/822,496 | LEMANSKI ET AL. | |
| | Examiner | Art Unit | |
| | Marsha M. Tsay | 1653 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *20 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *15-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's election with traverse of Invention II, Claims 1, 5-6, 10, 12-14, in Paper, filed October 20, 2004 is acknowledged. The traversal is on the ground(s) that the inventions share commonality because the sequences of the instant application are embedded in SEQ ID NO.5. A sequence search has indicated that SEQ ID NO. 6 and SEQ ID NO. 1 are embedded in SEQ ID NO.5. With applicants' election of Invention II, claims 1, 5-6, 10, 12-14, drawn to SEQ ID NO.5; Inventions I, III, and IV, are hereby rejoined and fully examined for patentability, as they are directed to the same parent sequence of SEQ ID NO.5. The restriction requirement made in the Office action between Inventions I-IV, mailed on September 20, 2004, is hereby withdrawn.

The requirement for Invention V is still deemed proper and is therefore made FINAL.

Claims 15-24 have been withdrawn from further consideration by the Examiner because these claims are drawn to non-elected inventions. Claims 1-14 are currently under examination.

Priority: The current application was filed April 12, 2004. This application claims priority to provisional application 60/462.171, filed April 10, 2003. The priority date is April 10, 2003.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-9 are drawn to purified nucleic acids encoding a myofibrillogenesis-inducing RNA (MIR) molecule having at least one functional activity of a native MIR molecule and claims 10-14 are drawn to the purified, encoded MIR molecule. The specification discloses SEQ ID NO.5 as a parent nucleotide sequence that is essential to the operation and function of the claimed invention. Two other nucleotide sequences, SEQ ID NO.1 and SEQ ID NO.6 are also disclosed, as being embedded in SEQ ID NO.5 and able to encode a functional MIR molecule. The specification also discloses that the purified nucleotide sequence can encode an RNA molecule having a secondary structure that permits specific binding to at least one MIR-binding protein. Neither claims 10-14 nor the specification disclose the structural features that are essential to the claimed function of the invention.

The language of the claims indicates that claims 1-9 are drawn to any nucleic acid that minimally contains SEQ ID NO.5, SEQ ID NO.1, or SEQ ID NO.6. The specification discloses that nucleotide sequences encoding a MIR molecule are encompassed by variants of a native MIR-encoding nucleic acid, including naturally occurring allelic variants, homologs, non-naturally occurring variants. These variants

can differ from a native MIR nucleic acid sequence by one or more bases, through deletions, additions, or substitutions. In addition, nucleic acid sequences from naturally occurring and non-naturally occurring allelic variants of a native MIR-encoding nucleic acid having at least 75% sequence identity with the native MIR-encoding nucleic acid are also disclosed by the specification. The specification does not provide further correlation between the structure and function of the RNA encoded by these nucleic acid sequences. One skilled in the art would not recognize from the disclosure that the Applicant was in possession of the genus of DNAs which comprise SEQ ID NO.5.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 7, 10, 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 10 are drawn to a functional activity of a native MIR molecule. It is unclear what this activity is. The specification (p.5) defines the term MIR molecule to mean nucleic acid in the form of an RNA molecule. RNA, strictly speaking, does not have any functional activities associated with it, except to be translated into protein. Applicants should clarify what is meant and encompassed by activity.

Claims 2 and 14 are drawn to a MIR-binding protein. It is unclear what a MIR-binding protein is and there is no clear example of such a protein. On page 14 of the

instant application, the specification describes MIR-binding proteins, but there are no specific MIR-binding proteins listed.

Claim 3 is indefinite because it is unclear what constitutes stringent hybridization conditions. On page 5 of the instant application, the specification defines "under stringent conditions" means under low, moderate, or high stringency conditions. However, there is no additional clarification of what is meant by low, moderate, or high stringency conditions.

Claim 7 is drawn to a purified nucleic acid wherein a portion of the polynucleotide sequence shares sequence identity with a second polynucleotide sequence that encodes a RNA splicing factor. There is no sequence reference available, therefore, it is unclear how a level of sequence identity can be established and assessed.

Regarding claim 10, the phrase "about" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "about"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 10, 11, 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Lemanski et al. (Lemanski et al. 1996 Biochem. Biophy. Res. Comm. 229: 974-981.).

Lemanski et al. teach the construction of a cDNA library in a pcDNAII vector with T7 and Sp6 polymerase promoters flanking the multiple cloning site (p. 976 results, fig, 1; claims 1, 10, 11, 13). Lemanski et al. teach the preparation of synthetic RNA from the cDNA of clone #4, where the RNA thus prepared was found to be active in rescuing mutant hearts as determined by their initiating contractions and forming organized myofibrils containing tropomyosin (p. 976, results; claims 1-2, 10, 11, 13). Lemanski et al. teach that a small specific synthetic RNA has the ability to promote myofibrillogenesis and rescue in vitro or in vivo cardiac mutant axolotl hearts when applied exogenously (p. 977; claim 1). Though Lemanski et al. do not specifically teach the hybridization of a nucleotide sequence of either SEQ ID NO.2 and SEQ ID NO.3 to the cDNA of Clone #4, this limitation is met by the Clone #4 cDNA. Since the Clone #4 cDNA by Lemanski et al. meets the limitations set forth by claim 1, the complement of the nucleotide sequence will hybridize to the nucleotide sequence of at least one of SEQ ID NO.2 and SEQ ID NO.3 (claim 3).

Claims 1, 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Lemanski et al. (Lemanski et al. 1996 Biochem. Biophy. Res. Comm. 229: 974-981.). Lemanski et al. disclose a nucleotide sequence of a clone #4 cDNA that encodes a myofibrillogenesis-inducing RNA (MIR) molecule (p. 976, fig. 1). The polynucleotide sequence depicted as SEQ ID NO.6, of the instant application, is disclosed in its entirety and embedded in the cDNA as disclosed by Lemanski et al. Though Lemanski et al. do not disclose the sequence similarity between the nucleotide sequence of Clone #4

cDNA and the RNA splicing factor SmN, the properties of the Clone #4 cDNA meet the limitations of Claims 7-9.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen Cochrane Carlson PhD

December 13, 2004

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER